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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,111	12/12/2003	Jong Kil	A03P1079US01	3654
36802	7590	11/01/2005		
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			EXAMINER GREENE, DANA D	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

17/15

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/736,111		KIL ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Dana D. Greene		3762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 11, 13, and 14 stand rejected under 35 U.S.C. §102(b) as being anticipated by Haefner et al. (US 6,169,918 B1, hereinafter “Haefner”). Haefner is considered to disclose:

a means for sensing a cardiac signal within the heart (see col. 2, ln. 45-55, Haefner). The disclosed cross-chamber sensing by atrial and ventricular electrodes is considered to anticipate the claimed atrial and ventricular electrodes because both sense atrial cardiac signals using electrodes implanted within the ventricles and ventricular cardiac signals using electrodes implanted within the atria, then combining the signals to emulate the surface EKG;

a means for distinguishing portions of the cardiac signal corresponding to atrial signals from those corresponding to ventricular signals (see col. 2, ln. 55 – col. 3, ln. 12, Haefner). The disclosed cross-chamber blanking technique is considered to anticipate the claimed means for distinguishing portions of the cross-chamber cardiac signal because both means set out differences between portions of the cardiac signals corresponding to atrial signals and those corresponding to ventricular signals;

a means for adjusting the relative amplitudes of the portions of the cross-chamber cardiac signal corresponding to atrial signals and the portions corresponding

to ventricular signals so as to yield an emulated surface EKG (see col. 6, ln. 8-40, Haefner). The disclosed peak adjustment circuit is considered to anticipate the claimed adjustment of the relative amplitudes because both enhance the performance of emulation by the implanted device by adjusting the amplitude to improve the operation of the device.

With reference to claims 7-9, Haefner is considered to disclose a method of distinguishing portions of cardiac signals comprising identifying atrial signals within the cross-chamber signal and identifying ventricular signals within the cross chamber signal (see col. 2, ln. 45-65, Haefner). The disclosed means cross chamber sensing is considered to anticipate the claimed method of distinguishing portions of cardiac signals because both make it easier to detect atrial or ventricular depolarization.

Referring to claims 11 and 14, Haefner is considered to disclose a method wherein adjusting relative amplitudes of the portions of the cardiac signal further comprises smoothing the adjusted signal (see col. 6, ln. 10-20, Haefner). The disclosed peak adjustment circuit adjusts the heart activity signal and resulting peak amplitudes.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-9 are rejected under 35 U.S.C. §103(a) as being unpatentable over

Haefner. Haefner is considered to disclose the claimed invention as discussed above, under the anticipatory rejection, except for the claimed predetermined ration range of

Art Unit: 3762

1:4 to 1:10. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the atrial and ventricular portions so as to achieve for a predetermined ration of peak atrial to peak ventricular signal amplitudes in the range of 1:4 to 1:10, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (see *In re Aller*, 105 USPQ 233).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haefner in view of Kroll et al. (US 6,813,514 B1, hereinafter "Kroll"). Haefner is considered to disclose the claimed invention as discussed above except for the claimed atrial electrode selected from a specific group. However, Kroll is considered to disclose:

The atrial electrode that is a right atrial tip electrode, a right atrial ring electrode, an SVC coil electrode, a left atrial ring electrode, a left atrial coil electrode or a transseptal atrial electrode and wherein the ventricular electrode is a right ventricular tip electrode, a right ventricular ring electrode, a right ventricular coil electrode, a left ventricular tip electrode, a left ventricular tip electrode, a left ventricular ring or a ventricular epicardial electrode (see col. 9, ln. 44-60, Kroll). It would have been obvious to one of ordinary skill in the art to combine the teachings of Haefner with the group in Kroll for the purpose of achieving left and right chamber sensing, pacing and shocking.

Claims 15 and 16 stand rejected under 35 U.S.C. over Haefner in view of Kroll. Haefner is considered to disclose:

Input circuitry operative to input a cardiac signal sensed by a device implanted within the patient using at least one electrode implanted within the heart (see col. 2, ln.

45-55, Haefner). The disclosed cross-chamber sensing by atrial and ventricular electrodes is considered to anticipate the claimed atrial and ventricular electrodes because both sense atrial cardiac signals using electrodes implanted within the ventricles and ventricular cardiac signals using electrodes implanted within the atria, then combining the signals to emulate the surface EKG.

Haefner is considered to disclose the claimed invention as discussed above except for the claimed emulation unit. However, Kroll is considered to disclose an EKG emulation unit operative to distinguish portions of the cross-chamber cardiac signal corresponding to atrial signals from those corresponding to ventricular signals (see col. 10, ln. 39-50, Kroll). The disclosed signals detected by the internal leads of the implanted device are considered to anticipate the claimed emulation unit because both configurations employ devices to sense atrial and ventricular signals. Further, the Kroll reference teaches emulation performed using a matrix-based technique that emulates individual signals. This is equivalent to the EKG emulation unit because the ability to emulate individual signals must include distinguishing portions of atrial signals from ventricular signals. In this connection, Kroll is considered to disclose:

an EKG emulation unit operative to adjust the relative amplitudes of the portions of the cross-chamber cardiac signal corresponding to atrial signals and the portions corresponding to ventricular signals so as to yield an emulated surface EKG (see col. 11, ln. 53-64, Kroll). The disclosed modification of operating parameters is considered to anticipate the claimed adjustment of relative amplitudes because both adjustments are made to customize the operation of the device to ultimately produce an emulated EKG. It would have been obvious to one of ordinary skill in the art to combine the

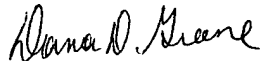
teachings of Heafner with the emulation unit of Kroll for the purpose of emulating a surface EKG using the internal cardiac signals sensed by an implantable medical device.

**Conclusion**

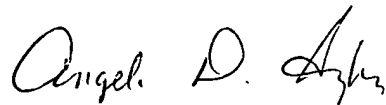
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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